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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,991	07/12/2000	Benjamin Pless	003-006	3292

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/614,991

Applicant(s)

PLESS ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 85-139 is/are pending in the application.
- 4a) Of the above claim(s) 5,24,27,36-39,85-114 and 119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-23,25,26,28-35,115-118 and 120-139 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 and 85-139 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election/Restrictions

Applicant's election of the invention of Group I (claims 1-39 and 85-87) and the further election of the species of Figures 71-73 is acknowledged. Applicant contended that claims 1-4, 6-23, 25, 26, 28-39, 87 and newly added claims 115-139 read on the elected species. However, in as much as claims 5 and 27 were withdrawn by the applicant, the examiner contends that claims 36-39 and 119, which recite similar limitations to that withdrawn in claims 5 and 27, should also be withdrawn. Cancellation of claims 40-84 is acknowledged.

Claims 5, 24, 27, 36-39, 85, 86, 88-114 and 119 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Related Applications

The examiner notes that there are several related applications which disclose and claim similar subject matter to the instant application. In the interest of thorough examination of the application claims, applicant is respectfully requested to provide the examiner with a complete listing of all applications containing a similar disclosure, as well as an indication of which applications contain claimed subject matter which may be specifically relevant to the pending claims of the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 122-124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 122 lack proper antecedent basis for "the concave surface". With regard to claim 8, it appears this claim should depend from claim 7 instead of claim 1. Similarly, claim 122 should depend from claim 121 instead of claim 115 in order to provide the necessary antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 11-18, 23, 25, 26, 31, 32, 35, 87, 115, 116, 125-132, 137 and 139 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcus et al ('484).

Marcus et al provide an ultrasonic delivery device for the treatment of cardiac tissue (Abstract). The device comprises a catheter with an ultrasonic transducer (or transducer array) at the distal end. The catheter includes temperature sensor means to monitor temperature (col. 9, lines 5-24). The examples also include methodologies which include multiple applications of ultrasonic energies with varying frequencies and power ranges (columns 8 and 9). The multiple activations inherently include a movement of the focus of the ultrasound energy (i.e. to a new lesion site). Also, the

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Marcus et al device includes a plurality of electrodes located on the distal end to measure tissue impedance and provide information regarding the mapping of the tissue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 28, 29, 125-130 and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484).

Marcus et al disclose several studies which set forth the methodologies used in treating cardiac tissue. These methodologies include multiple deliveries of energies at various frequencies, time durations, energy levels, etc. The examiner maintains that one of ordinary skill in the art would obviously arrive at any reasonable combination of parameters as would befit the procedure. In particular, it is noted that the Marcus et al examples specifically disclose using different frequencies, treatment duration and energy levels within any treatment regimen. To have provided any particular treatment regimen as deemed appropriate for a given procedure would have been an obvious consideration for one of ordinary skill in the art.

Claims 7-10 and 121-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484) in view of the teachings of Cline et al ('845) and Sanghvi et al ('692).

Marcus et al fail to teach the use of an ultrasonic transducer with a concave face. Cline et al and Sanghvi et al both disclose ultrasonic transducer devices for the ablation of tissue. In particular, the transducers include concave faces for focusing energy to tissue.

To have provided the Marcus et al catheter with a transducer with a concave surface for focusing energy to tissue would have been an obvious design consideration for one of ordinary skill in the art in view of the teachings of Cline et al and Sanghvi et al.

Claims 19-22, 33, 34 and 133-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcus et al ('484) in view of the teaching of Negus et al ('848).

Marcus et al fail to disclose the steps of monitoring tissue thickness during the procedure. Negus et al disclose a device for the ablation of cardiac tissue, which may utilize ultrasonic energy to treat tissue. Further, Negus et al specifically disclose the steps of monitoring tissue depth during the treatment (columns 5 and 6).

To have monitored tissue depth during the ablation of cardiac tissue with the Marcus et al device would have been an obvious modification for the skilled artisan, particularly since Negus et al disclose the step of monitoring tissue depth during ultrasonic ablation of cardiac tissue.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cain et al ('657) disclose the use of focused ultrasonic energy for

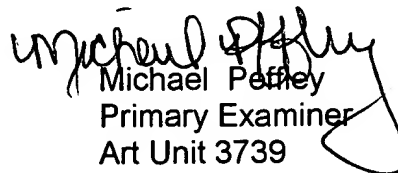
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the ablation of cardiac tissue. Hissong ('531) and Sanghvi et al (WO 02/24050) disclose focused ultrasonic energy devices for the treatment of tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
July 16, 2002